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10/667,034	09/22/2003	James D. Ralph	SPINE 3.0-441 CONT CONT	1511
51640	7590	01/31/2011	EXAMINER	
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			NELSON, CHRISTINE L	
			ART UNIT	PAPER NUMBER
			3775	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,034	Applicant(s) RALPH ET AL.	
	Examiner CHRISTINE L. NELSON	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,9,10,13,18,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,7,9,10,13,18,19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on September 22, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendments and arguments submitted on November 12, 2010.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “at least one relative angle designation mark on the upper surface and at least one relative angle designation mark on the lower surface” must be shown or the feature(s) canceled from the claim(s). The drawings do not contain any feature that is labeled as such. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New

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Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation of "at least one relative angle designation mark on the upper surface and at least one relative angle designation mark on the lower surface" is not disclosed in the specification. Paragraph [0040] states "at least two relative angle designation marks on at least one of said upper and lower surfaces."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US Patent 6,425,920) in view of Gross et al (US Patent 5,306,308).

Regarding Claims 1 and 2, Hamada discloses (Figures 58-60) an intervertebral spacer (701) that is porous ([30], lines 4-11, noting that harvested allograft bone is porous) with a beveled edge (sloping outward as seen in Figure 60), a spacer body with a central bore (707) passing through the upper (703) and lower (705) surfaces where both of the surfaces are substantially flat, and the upper and lower surfaces diametrically tapered (as seen in Figure 60). Hamada fails to disclose at least one relative angle designation mark on the upper surface and at least one relative designation mark on the lower surface. Gross teaches at least one relative angle designation mark on the upper surface and at least one relative designation mark on the lower surface (formed by the edges of the recess, 12, as seen in Figure 4b). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Hamada with the teaching of the recess of Gross, to avoid blocking nerve tracks by the implant.

Regarding Claims 4, 6, 7, 18 and 19, Hamada does not disclose a tapered annular groove. Gross et al teaches (Column 2, Lines 41-45) that a tapered axially annular groove (7') simplifies the surgical procedure by allowing the implant to be held and inserted by surgical forceps. Additionally, Gross has radially outwardly extending

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division lines, which would function as relative angle designation marks. Further still, Gross teaches a recess (Figure 4b, 12) at least one relative angle designation mark on the upper surface and at least one relative designation mark on the lower surface that extend from the wall of the annular groove. Though not extending from the upper to the lower surface, these are evenly spaced and would provide the surgeon with a view of relative angle. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to combine the tapered medial groove and also the relative angle designation marks of Gross with the device of Hamada to allow surgical forceps to grip the implant and assist with placement by having relative angle marks, thereby facilitating the surgical procedure.

Regarding Claims 9, 10, 13, and 21, Hamada does not disclose an upper radial flange disposed between the upper surface and the axially medial groove and a lower radial flange disposed between the lower surface and the axially medial groove, where the at least one relative angle designation mark extends through at least one of the upper and lower radial flanges. Gross teaches an upper radial flange (Figure 4d – not labeled, but formed by the upper portion of the axially medial groove) disposed between the upper surface and the axially medial groove and a lower radial flange (Figure 4d – not labeled, but formed by the lower portion of the axially medial groove) disposed between the lower surface and the axially medial groove, where the at least one relative angle designation mark extends through at least one of the upper and lower radial flanges (Figure 4d). It would have been obvious to one having ordinary skill in the art at

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the time the invention was made to combine the flanges (that occur as part of the axially medial groove) of Gross with the invention of Hamada as described above.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4, 6, 7, 9, 10, 13, 18, 19, and 21 have been considered but are not persuasive.

The new limitation added in claims 1, 4, and 9 that states "at least one relative angle designation mark on the upper surface and at least one relative angle designation mark on the lower surface" is not disclosed in the specification. Paragraph [0040] states "at least two relative angle designation marks on at least one of said upper and lower surfaces." These limitations are NOT the same. The specification indicates that the at least two relative angle designation marks are on *either* the top or the bottom surfaces - not one on each surface and not extending from a wall of the annular groove. Regardless, Hamada in view of Gross discloses the invention as claimed, as the two edges of the recess (figure 4b, 12) of Gross would form two relative angle designation marks on the top and two relative angle designation marks on the bottom. Furthermore, Gross discloses the angle designation marks as presented in the specification, as Gross teaches multiple grooves that could be used to determine positioning on both the top and bottom (Figures 3 and 4d).

Furthermore, the examiner fails to see where Figure 4A shows "two relative angle designation marks, one on each of the upper and lower surfaces." Figure 4A is a top view of the device and therefore the upper and lower surfaces can not both be

seen. Multiple angle designation marks on either the top or bottom surfaces are not shown or labeled.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE L. NELSON whose telephone number is (571)270-5368. The examiner can normally be reached on Monday through Friday 7:30 to 5:00 - first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINE L. NELSON/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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